POLICY AND PROCEDURE

DEPARTMENT: Clinical Pharmacy Services	**DOCUMENT NAME:** Drug Utilization Review Policy
PAGE: 1 of 9	**REPLACES DOCUMENT:**
APPROVED DATE 02/27/2018	**RETIRED:**
EFFECTIVE DATE: 06/19/2006	**REVIEWED/REVISED DATE:** 2/08; 9/08; 9/09; 9/10; 9/11; 9/12; 8/13; 10/13; 12/13; 1/14; 1/15; 11/15; 7/16; 10/16; 11/16; 5/17
PRODUCT TYPE: Medicaid	**REFERENCE NUMBER:** PA.EPS.PHARM.05

SCOPE:
This policy applies to Envolve Pharmacy Solutions Clinical Pharmacy Department drug utilization review programs.

PURPOSE:
Define the process of Drug Utilization Review (DUR) at Envolve Pharmacy Solutions.

POLICY:
Drug Utilization Review (DUR) is a structured, continuous program that reviews, analyzes, and interprets medication use against established medical standards and criteria.

DUR program activities will be approved by the Envolve Pharmacy P&T Committee with the goal of enhancing safety, appropriateness, and cost effective use of prescription medications. All activities will be developed utilizing appropriate clinical protocols, FDA approved labeling, and evidence-based guidelines for prescription drug use.

DUR program activities will consist, at a minimum, of prospective, concurrent, and retrospective medication reviews, targeted educational interventions when appropriate, and other activities as requested by the plan sponsor. All Envolve Pharmacy Solutions DUR functions shall be performed in conjunction with Health Plan DUR programs.

The results of the drug utilization reviews will be communicated to the Health Plan, physician, and/or member based upon the type of activity conducted. Any errors of clinical significance will be disclosed to the consumer directly by the Health Plan. Any errors that are identified during the drug utilization review process will be monitored and reported to the QI/UM Committee.

Envolve Pharmacy Solutions shall not disclose or publish individual medical records or any other confidential medical information in the performance of utilization review activities except as provided in the Health Insurance Portability and Accountability Act, Subtitle F, sections 261 to 264, Centene Corporate policies, and other applicable laws and administrative regulations.

PROCEDURE:
DUR Objectives:
Drug utilization review goals include:

- Identify and analyze utilization patterns in order to impact prescribing, dispensing, and overall drug utilization practices.

- Identify and intervene with high-risk members, prescribers, and pharmacies to improve safety and long-term health care.
- Improve prescribing trends by educating prescribers and alerting them to potential problems.
- Improve cost-effectiveness and quality of members' health care.
- Advance education and communication among prescribers, pharmacists, health plans, and members to enhance optimal health care.
- Improve overall quality of care by providing monthly, quarterly, and annual reports to health plans.

Prospective Drug Utilization Review (ProDUR):
ProDUR activities occur prior to a prescriber providing a drug, or before a member receives a prescription. ProDUR Activities encourage the reduction of improper drug selection by supplying providers with certain tools to assist their selection of an appropriate drug regimen for each patient. Envolve Pharmacy Solutions utilize ProDUR tools such as, but not limited to:

- Preferred Drug or Formulary Lists and Portals – these lists and portals assist providers in choosing drug regimens that are safe, effective, and economical for members. Providers may reference each plan-specific website or portal for a current Preferred Drug List (PDL) or Formulary.

- Prior Authorization Review– A medication evaluation process allowing prescribers to work in conjunction with the Envolve Pharmacy Solutions Utilization Management Team to determine the most appropriate regimen for a member. Prior authorization reviews often target high-risk and/or high-cost medications that may require additional therapy considerations. Part of the Prior Authorization process may include the use of 'step-therapy' to ensure that clinical guidelines and protocols, designed to maximize patient benefit, are followed. For more information refer to the Prior Authorization Review Process Policy (EPS.PHARM.03).

Concurrent Drug Utilization Review (CDUR):
As a part of CDUR, Envolve Pharmacy Solutions utilizes an electronic claim adjudication process incorporating 'edits' designed to detect, flag, and stop inappropriate prescribing and utilization. CDUR occurs at the point of sale (POS) and includes real-time 'edits', including adjudication hard stops, and provider messages to assist dispensing pharmacists.

Envolve Pharmacy Solutions utilizes a CDUR plan that is managed by an outside vendor, attached below and hereby incorporated into this policy, which is managed by an outside vendor,

however, this plan may be supplemented with other CDUR activities or tools that include, but are not limited to:

- Alerts from Medi-Span – A clinical drug information database, containing up-to-date and comprehensive medication information that is capable of alerting pharmacists of certain drug-related issues. The Medi-span database is supplemented with Health Plan-specific therapy considerations to ensure clinical appropriateness and safety of a member's therapy. Alerts may include, but are not limited to those regarding:
  - Therapeutic appropriateness as determined by the pharmacist's clinical judgment
  - Availability of therapeutic interchanges
  - Availability of generic utilization
  - Over and under utilization
  - Excessive doses/high dosages of therapy
  - Dose optimization
  - Duplicate therapy

  - Drug-disease contraindications
  - Drug-age precautions
  - Drug-pregnancy precautions
  - Drug-drug interactions
  - ~~Drug-gender alerts~~
  - Drug-allergy interactions
  - Inappropriate durations of therapy
  - APAP overuse screening
  - Clinical abuse or misuse
  - Regulatory limitations
  - Benefit design

- Therapeutic Interchange Program – messaging at point-of-sale (POS) notifying pharmacists a prescription claim is outside Preferred Drug Lists or Formularies. Messages are designed to **suggest** an appropriate, preferred, and cost-effective drug alternative to allow pharmacists and prescribers to coordinate care and ensuring optimal drug therapy.

- Clinical Drug Restrictions – restrictions due to benefit designs that are programmed to prevent unsafe and inappropriate use of medications. Restrictions aim to promote drug safety, cost effective medication use, and to prevent inappropriate utilization and prescribing. Restrictions cannot be overturned at the pharmacy POS, instead they require further review by the prescriber and coordination of care with managed care specialists (i.e. prior authorization pharmacist, health plan medical directors, etc.).

Retrospective Drug Utilization Review (RetroDUR)
RetroDUR is conducted monthly, quarterly, and as needed or required by the Health Plan in order to identify patterns of inappropriate or medically unnecessary care. RetroDUR evaluates claims data of individual members, physicians, and pharmacy dispensings. Review allows for evaluation of therapeutic appropriateness, cost-effectiveness, quality of care, fraud and abuse, over/underutilization, adverse drug events, prescribing errors of clinical significance, and outcomes management, and guides initiatives to improve medication use outcomes. Activities resulting from RetroDUR may include, but are not limited to:

- Outreach Letters and Programs – Communications via letter or other medium focused on improving medication utilization practices at the member, provider, or health plan level. This

intervention is performed by either Envolve Pharmacy Solutions or the individual Health Plans.

- Member Lock-In Programs– In collaboration each Health Plans, this member focused intervention restricts members to using one prescriber, one pharmacy, or both for obtaining a narcotic prescription(s). Lock-ins are generally applied to members at high-risk of medication abuse or misuse are often locked in, making their benefit only available when using the designated prescriber or pharmacy.

REFERENCES:

- Evaluation of Drug Utilization Review Programs:
  Robert Berringer, Ellen Friedla, and Karen Rich
  JAMA. 2004;291:184-185
- URAC PBM Standards (Version 2.2): DrUM 1, 4, 5, & 17.
- EPS.PHARM.03
- EPS.COMP.06
- EPS.PHARM.15
- 42 CFR § 423.153(b)(1)(2); (c)(2)(i-vi); (c)(3)
- 42 CFR § 456.700 *et seq.*
- 42 CFR § 438.3
- 19 USC 1927(g)
- Prescription Drug Benefit Manual: Chapter 7 Quality Assurance Requirements:
  - Section 20.3 Concurrent Drug Utilization Review;
  - Section 20.4 Retrospective Drug Utilization Review.
- Health Insurance Portability and Accountability Act, Subtitle F, sections 261 to 264

ATTACHMENTS: N/A

DEFINITIONS:

- **Overutilization** - use of a drug in a quantity, strength, or duration that is greater than necessary to achieve a desired therapeutic goal or that puts the beneficiary at risk of a clinically significant undesirable effect, or both.
- **Underutilization** - use of a drug by a beneficiary in insufficient quantity, strength, or duration to achieve a desired therapeutic goal or that puts the beneficiary at risk of a clinically significant undesired effect, or both.
- **Soft Edits** – Drug restrictions that can be over-turned by the pharmacist at point-of-sale.

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- **Hard Edits** – Drug restrictions that cannot be over-turned without prior authorization approval.
- **DACON** – Daily average consumption of prescription medication.

REVISION LOG

REVISION	DATE
Amy Janiak, Pharm D.	2/11/08
Reviewed content.	9/18/08
Revised content.	9/28/09
Revised **Prospective Drug Utilization Review (ProDUR)** sentence. Old "ProDUR helps deter improper drug selection by providing physicians with tools in order to select the most appropriate regimen for his/her patient." Revised to read "ProDUR helps deter improper drug selection by providing physicians with tools to assist in the selection of the most appropriate regimen for his/her patient"; Revised References for URAC PBM Standards.	9/28/10
Added the following to Policy section: "US Script shall not disclose or publish individual medical records or any other confidential medical information in the performance of utilization review activities except as provided in the Health Insurance Portability and Accountability Act, Subtitle F, sections 261 to 264, Centene Corporate policies, and other applicable laws and administrative regulations"; Updated URAC standards.	09/07/11
Reviewed content.	09/10/12
Under Scope: Added "drug utilization review programs"	08/12/13
Under Policy: Added the words "claims", "FDA approved labeling, and", "due to differing", and "Plan requirements". Deleted the words "Essentially", "attempts to", "because of differences in", and "Plans".	08/12/13
Under Procedure: Prospective Drug Utilization Review – Deleted "breakdowns in patient safety" and added "drug misadventures".	08/12/13

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Prospective Drug Utilization Review second bullet point – Deleted "specialized pharmacists" and added "licensed clinicians". Retrospective Drug Utilization Review first bullet point – Replaced "medicine" with "criteria". Deleted "etc." and added "availability of costs effective…" Retrospective Drug Utilization Review second bullet point – Deleted the word "narcotic." DUR Objectives first bullet point – Added "utilization".	
Under Procedure: Concurrent Drug Utilization Review first bullet – Added "drug-gender precautions" and added "such as drug-disease contraindications." Concurrent Drug Utilization Review second bullet – Deleted "Medication" and added "Therapeutic" and added "included as a component of the benefit design." Concurrent Drug Utilization Review third bullet – Added "and include duration of treatment edits related to maximum dosing, quantity limits, and early refills".	10/24/13
Under Policy: Added: "The results of the drug utilization reviews will be communicated to the Health Plan, physician, and/or consumer based upon the type of evaluation conducted (Prospective, concurrent, or retrospective). Any errors that are identified during the drug utilization review process will be monitored and reported to the QI/UM Committee." **Under Procedure:** Added: "prescribing errors of clinical significance" to Retrospective Drug Utilization Review (RetroDUR)	12/10/13
Under Policy: Added: "Any errors of clinical significance will be disclosed to the consumer directly by the health plan."	01/22/14
Reviewed for content.	01/22/15
Reviewed for content.	11/24/15
Under Procedure: Added: "Please reference the plan-specific website for a current Preferred Drug List (PDL) or Formulary."	07/01/16

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Added: "Please reference the Pharmacy Prior Authorization Review Process policy (USS.PHARM.03)." Added: "RetroDUR is conducted on an as-needed basis and by monthly, quarterly, and annual examinations of member electronic claims data and other available records, in order to identify patterns of inappropriate or medically unnecessary care." Added: "Improve overall quality of care by providing monthly, quarterly, and annual reports to health plans." Added references: USS.PHARM.03	
Due to rebranding of US Script Inc. to Envolve Pharmacy Solutions, replaced "US Script Inc./USS" with "Envolve Pharmacy Solutions" throughout document.	10/17/16
Under Concurrent Drug Utilization Review (CDUR): Revised Medi-Span section to read: "The CDUR is used during claim adjudication to make sure that the member is not receiving a drug that may be harmful to them. During adjudication, CDUR edits are checked simultaneously with the other plan edits. These alerts include: − Therapeutic appropriateness as determined by the pharmacist's clinical judgment − Therapeutic interchange − Generic use − Excessive doses/high dosages − Drug dosages − Dose optimization − Duplicate therapy − Drug-disease contraindications − Over and under utilization − Drug-age precautions − Drug-pregnancy precautions − Drug-drug interactions − Drug-gender alerts − Drug-allergy interactions − Duration of therapy − Clinical abuse or misuse − Regulatory limitations − Benefit design"	11/7/2016

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POLICY AND PROCEDURE APPROVAL

The electronic approval retained in Centene's P&P management software, is considered equivalent to a physical signature.

Envolve Pharmacy Solutions, Vice President of Clinical Pharmacy Solutions: Approval on file